Declaration of Conformity for CE/UKCA Marking

Machinery Directive 2006/42/EU (Safety) / Machine Regulation SI 2008 Nr. 1597
Low Voltage Directive 2014/35/EU / Low Voltage Regulation SI 2016 Nr. 1101
EMC Directive 2014/30/EU / EMC Regulation SI 2016 Nr. 1091

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We herewith declare that the ***PuraLev® Console LCO-i100***, in its configurations as listed below is in conformity with the above mentioned *European Directives* and *UK Statutory Instruments*. The console is thought to be used in laboratory and industrial production environment of Life Science markets like Biotech and Pharmaceuticals.

Part Name	***Description***
LCO-100.x-yy	*LCO-i100.x-yy* with x = various hardware configuration options and yy = various firmware options. Consoles with 24 VDC for up to 160W supply input. *Note: The standard specified AC/DC power supplies for 50 and 160W are commercially available NRTL certified components.*
Drivers	Compatible *CE* certified *IPD-30.x* drivers (24 VDC) of the *PuraLev® i30SU* pump system. Compatible *CE* certified *IPD-100.x* drivers (24 VDC) of the *PuraLev® i100SU* pump system. Compatible *CE* certified *IPD-600.x* drivers (48 VDC) of the *PuraLev i600SU* pump system. Compatible *CE* certified *IPD-2000.x* drivers (200-240 AC) of the *PuraLev i2000SU* pump system.
Pump Heads	Single-Use *DCP-30.x* pump heads of the *PuraLev® i30SU* pump system. Single-Use *DCP-200.x* pump heads of the *PuraLev® i100SU* pump system. Single-Use *DCP-600.x* pump heads of the *PuraLev® i600SU* pump system. Single-Use *DCP-2000.x* pump heads of the *PuraLev® i2000SU* pump system.
Flow Sensors	Clamp-on flow sensors of the *LEVIFLOW® LFSC-D and LFSC-iX* Series. Single-Use sensors of the *LEVIFLOW® LFS-SU* Series.
Pinch Valves	Pinch valves of the *LPVS-i* Series.
Accessories	Various signal adaptor cables.

Machinery Directive 2006/42/EU – Machinery Regulation SI 2008 Nr. 1597

The machinery directive/regulation essentially has been followed by a risk analysis, according mitigation actions and a user manual for safe operation. For the design and testing the following standards are used as a guideline:

ISO 12100	Safety for machinery – principles for risk assessments: used for system risk analysis.
IEC/EN 60529	Degree of protection provided by enclosure (IP code).

Low Voltage Directive 2014/35/EU – Low Voltage Regulation SI 2016 Nr. 1101

The low voltage directive/regulation essentially has been followed by a risk analysis, electrical safety testing and a user manual for safe electrical operation. For the design and testing the following standards are used as a guideline:

IEC/EN 61010-1	Safety requirements for electrical equipment: tested at certified 3rd party laboratory.
UL60950-1	Fulfilled by the specified standard commercially available AC/DC powers supplies.
ISO 12100	Safety for machinery – principles for risk assessments: used for system risk analysis.

EMC Directive 2014/30/EU - EMC Regulation SI 2016 Nr. 1091

The following standards of the EMC directive/regulation are tested and confirmed at a certified laboratory:

IEC 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements

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